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510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Date Prepared: November 8, 2011
Name: PFM Medical, Inc
Address: 1815 Aston Ave Ste 106.
Carlsbad, CA 92008
CONTACT PERSON: SALVADORE F. PALOMARES, RAC
Phone: (760) 758-8749

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Veta Peritoneal Dialysis Catheter
Common Name: Catheter, Peritoneal Dialysis, Single-Use
Classification Name: Peritoneal Dialysis System and Accessories

Equivalent Devices:
Manufacturer: Quinton, Inc. (now Covidien)
Name: Quinton Tenckhoff Peritoneal Catheter
510(k) #: K812607

Manufacturer: PFM Medical, Inc.
Name: ASEPT Peritoneal Drainage System
510(k) #: K093796

Manufacturer: Denver Biomedical (now Cardinal Health)
Name: Pleurx Peritoneal Catheter Kit and Pleurx Drainage Kits
510(k) #: K051711

Device Description:
Veta™ Peritoneal Dialysis Catheters are side-ported silicone catheters with a single and double retention cuff, available in a range of lengths and French sizes and in either a straight or spiral tip configuration.

Intended Use:
The Veta Peritoneal Dialysis Catheter is indicated for acute and chronic access to the peritoneal cavity. The Veta Peritoneal Dialysis Catheters will be used to drain and infuse fluid during peritoneal dialysis procedures.

Performance Data:
In vitro testing was performed on the Veta Peritoneal Dialysis Catheter to assure reliable design and performance in accordance with BS EN 1618-1997. Testing includes leakage, flow rate, tensile strength, and corrosion.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility:
Materials used in the Veta Peritoneal Dialysis Catheter meet the requirements of ISO 10993 or identical to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Salvadore Palomares, RAC
Director of Regulatory Affairs
PFM Medical, Inc.
1815 Aston Ave. Suite 106
CARLSBAD CA 92008

MAR 13 2012

Re: K113354
Trade/Device Name: Veta Peritoneal Dialysis Catheter
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: January 26, 2012
Received: January 27, 2012

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K113354

510(k): K113354

Device Name: **Veta Peritoneal Dialysis Catheter**

Indications for Use: The Veta Peritoneal Dialysis Catheter is indicated for acute and chronic access to the peritoneal cavity. The Veta Peritoneal Dialysis Catheters will be used to drain and infuse fluid during peritoneal dialysis procedures.

Prescription Use ___X___ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, Urological Devices
510(k) Number K113354